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No. 02-342

IN THE

Supreme Court of the United States

KEY PHARMACEUTICALS, SCHERING-PLOUGH CORPORATION, and SCHERING CORPORATION,

Petitioners,

v.

FREDERICK D. EDWARDS, M.D.,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE COURT OF APPEALS OF THE STATE OF OREGON

BRIEF IN OPPOSITION

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PARTIES TO THE PROCEEDINGS

As the Petition notes, Petitioners are Key Pharmaceuticals, Schering-Plough Corporation and Schering Corporation (collectively "Key"). They were appellants in the Oregon Court of Appeals, appealing from judgments entered against them as defendants in a negligence and strict products liability lawsuit brought by Paul R. Bocci, Jr., as guardian ad litem for Paul R. Bocci, III, an incapacitated individual, and as cross-claim defendants on the negligence and fraud cross-claims brought by defendant Frederick D. Edwards, M.D.

Respondent is Dr. Frederick D. Edwards, who, together with his employer, The Eugene Clinic, was dismissed as a defendant from Bocci's lawsuit before the case was submitted to the jury, but who remained as a cross-claim plaintiff in the trial court and a cross-claim respondent on appeal on his cross-claim against Key.

Initially, Bocci was also a respondent on Key's appeal, but Key settled with Bocci, and Key's appeal against him was dismissed before the Oregon Court of Appeals issued its first decision, *Bocci v. Key Pharmaceuticals, Inc.*, 158 Or. App. 521, 974 P.2d 758 (1999) (*"Bocci I"*).

Other parties listed as defendants in the caption in the Oregon trial and appellate courts were Miles, Inc., Miles Pharmaceutical Division, Legacy Health System, and Legacy Immediate Care Clinic, each of whom, on Bocci's motion in the trial court, was dismissed with prejudice.

Finally, although not a party to any of the proceedings below, the Department of Justice of the State of Oregon is listed as a judgment creditor for that portion of the punitive damages award to which the Criminal Injuries Compensation Account is entitled pursuant to Or. Rev. Stat. § 18.540 (1987). *See* Pet. App. 131a.

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BRIEF IN OPPOSITION

The Petition should be denied because the questions Key presents are premised upon a distorted presentation of the facts and record and upon arguments and objections that were neither pressed nor passed upon below, and because there are no compelling reasons warranting review by this Court. The Oregon Court of Appeals did not decide any important question of federal law in a way that conflicts with any decision of this Court, nor did it decide any new federal question that has not been, but should be, decided by this Court. To the contrary, the Oregon Court of Appeals, specifically applying decisions of this Court, conducted a *de novo* review and affirmed the punitive damages awarded in this case. *Bocci v. Key Pharmaceuticals, Inc.*, 178 Or. App. 42, 35 P.3d 1106 (2001) ("*Bocci II*"), Pet. App. 1a-11a.

OPINIONS BELOW

Judge William C. Snouffer of the Oregon Circuit Court for the County of Multnomah entered unreported judgments on the jury verdicts against Key on Bocci's negligence and strict products liability claims, Pet. App. 119a-126a, and on Dr. Edwards' negligence and fraud cross-claims in September 1994,[1] Pet. App. 127a-132a. Judge Snouffer also denied Key's motions for judgment notwithstanding the verdicts, new trial, and/or remittitur in an unreported "Opinion Denying Post-Trial Motions."[2] Opp. App. 1a-6a.

The Oregon Court of Appeals, sitting en banc, affirmed the trial court's judgments by an equally divided court.[3] *Bocci v.*

1. Under Oregon law, a physician may recover damages for harm caused by a drug manufacturer's negligent or intentional tort. *Oksenholt v. Lederle Labs*, 294 Or. 213, 656 P.2d 293 (1982).

2. The portion of that opinion relating to the trial court's review of the constitutionality of the punitive damages awards is only partially set forth in petitioners' appendix, Pet. App. 89a-91a, but is fully set forth in the appendix to this opposition, Opp. App. 1a-6a.

3. The en banc Court of Appeals divided only over issues related to the "Covenant Not to Enforce Judgment and Separate Loan (Cont'd)

Key Pharmaceuticals, Inc., 158 Or. App. 521, 974 P.2d 758 (1999) ("*Bocci I*") (Pet. App. 12a-70a). Key petitioned for review and the Oregon Supreme Court held the petition in abeyance pending its decision in *Parrott v. Carr Chevrolet, Inc.*, 156 Or. App. 257, 965 P.2d 440 (1998), *rev. allowed*, 328 Or. 418 (1999). After the Oregon Supreme Court issued its decision in *Parrott v. Carr Chevrolet, Inc.*, 331 Or. 537, 17 P.3d 473 (2001) (Pet. App. 133a-168a), setting forth the appropriate standards in Oregon for post-verdict judicial review of punitive damages awards following this Court's decision in *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559 (1996), it remanded this case to the Oregon Court of Appeals for further consideration in light of *Parrott*. *Bocci v. Key Pharmaceuticals, Inc.*, 332 Or. 39, 22 P.3d 758 (2001) (Pet. App. 71a-72a).

On remand, the Oregon Court of Appeals unanimously affirmed Dr. Edwards' punitive damages award, based upon its *de novo* review of the award in light of: (1) the Oregon Supreme Court's decision in *Parrott*; (2) this Court's decisions in *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *BMW of N. Am. v. Gore*, 517 U.S. 559 (1996), and *Honda Motor Co., Ltd. v. Oberg*, 512 U.S. 415 (1994) ("*Oberg*"); (3) the arguments of Key that were properly preserved; and (4) the facts as the jury was entitled to find them. *Bocci v. Key Pharmaceuticals, Inc.*, 178 Or. App. 42, 35 P.3d 1106 (2001) ("*Bocci II*") (Pet. App. 1a-11a). The Oregon Supreme Court denied Key's second petition for review. *Bocci v. Key Pharmaceuticals, Inc.*, 334 Or. 260, 47 P.3d 486 (2002) (Pet. App. 73a).

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Agreement" between Bocci, Dr. Edwards, and Dr. Edwards' insurer. The dissent did not discuss, criticize, or express any disagreement with the concurrence's resolution of the punitive damages issues Key raised. *See Bocci I*, 158 Or. App. at 774-83, Pet. App. 12a-70a. Because Key settled with Bocci before the Court of Appeals issued its decision, Bocci was dismissed from the appeal, and no issues directly related to the verdict in his favor were addressed in *Bocci I*. *Id.* at 523 n.2, 528, Pet. App. 14a, 20a.

COUNTERSTATEMENT OF THE CASE

In its Petition, as it did throughout the proceedings below, Key makes arguments that are premised on a distorted presentation of the issues, claims, and evidence in the case. Key still fails to acknowledge that the jury's verdicts and punitive damages awards for both Dr. Edwards and Bocci were the result of proof of Key's aggressive and, despite repeated FDA warnings, persistent promotion of its drug Theo-Dur without adequate warnings, and with material misrepresentations as to the drug's safety.

Key still attempts to blame Dr. Edwards, despite the jury's finding that he was zero percent at fault.[4] Key also ignores that the jury found clear and convincing evidence that Key acted with wanton disregard for the health, safety and welfare of others, and knowingly withheld or misrepresented information known to be material and relevant to the harms suffered.[5] Pet. App. 123a, 129a.

Under Rules 14.1(g) and 14.4, Key's failure to accurately set forth the facts clearly material to consideration of the

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4. Key also continues to minimize Dr. Edwards' damages and mischaracterize his claim as one only for emotional distress, ignoring that his claim was for injury to reputation with accompanying emotional distress for which the jury awarded him $500,000 in noneconomic compensatory damages. Incredibly, Key also now attempts to minimize Bocci's injury, characterizing it as "brain damage resulting in short-term memory loss," and ignoring the evidence of Bocci's severe brain damage that has left him severely disabled, with no short term memory, with a permanent seizure disorder, incapable of unassisted living or unsheltered employment, and, worst of all, cognitively aware that he is brain damaged, and for which the jury awarded over $9 million in total compensatory damages. While Key self-servingly minimizes Bocci and Dr. Edwards' damages, and characterizes Dr. Edwards' compensatory damages award as "extremely generous," Pet. at 11, it was for the jury, not Key, to decide what amounts were needed to appropriately compensate Bocci and Dr. Edwards for their injuries.

5. Despite that finding, Key, to the extent it makes any reference in its Petition to its own conduct, downplays its reprehensibility and suggests, that, at worst, it "overstated" Theo-Dur's safety. *See* Pet. at 2.

questions presented, including the facts relating to the reprehensibility of its conduct,[6] is a sufficient reason to deny Key's petition. Nevertheless, to counter Key's distorted summary of the facts, and mindful of the admonishment in Rule 15.2, Dr. Edwards offers the following summary, and adopts and incorporates the facts stated by the Oregon Court of Appeals in *Bocci I*, 158 Or. App. 521, Pet. App. 12a-70a.

A. Counter-Summary of the Facts

In September 1994, the jury returned verdicts against Key. On Bocci's negligence and strict liability claims, the jury found Key 65% and Bocci 35% at fault and awarded Bocci total compensatory damages of $9,033,305 and punitive damages of $35 million, the full amount that he had alleged and prayed for.[7] Pet. App. 121a-124a. On Dr. Edwards' negligence and fraud cross-claims, the jury found Key 100% and Dr. Edwards 0% at fault, and awarded Dr. Edwards $500,000 in noneconomic compensatory damages and $22.5 million in punitive damages, less than the $35 million he had alleged and prayed for. Pet. App. 127a-130a. The jury explicitly found clear and convincing evidence that Key had "acted with wanton disregard for the health, safety and welfare of others," and "in violation of applicable FDA regulations, knowingly withheld from or misrepresented to the FDA or prescribing physician information known to be material and relevant to the harm that plaintiff allegedly suffered." Pet. App. 123a, 129a. Ample evidence supported the jury's determinations.

Theophylline, a drug used to treat asthma, has a narrow therapeutic range — most patients need serum levels of at least

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6. As this Court made clear in *BMW*, 517 U.S. at 575, "[p]erhaps the most important indicium of the reasonableness of a punitive damages award is the degree of reprehensibility of the defendant's conduct."

7. Under Oregon law, a verdict may not exceed the amount alleged and prayed for in the complaint and juries are so instructed. *Wiebe v. Seely*, 215 Or. 331, 357, 335 P.2d 379 (1959); *Lovejoy Specialty Hosp., Inc. v. The Advocates for Life*, 121 Or. App. 160, 167, 855 P.2d 159, *rev. denied*, 318 Or. 97 (1993), *cert. denied*, 511 U.S. 1070 (1994).

10 mcg/ml to prevent symptoms, but levels above 20 mcg/ml are toxic. Ex. 8, p. 6; Tr. 1004-06, 1604. Saturation kinetics is a factor in theophylline toxicity,[8] Tr. 3028-30, as Key well knew, Ex. 81, pp. 26, 48; Ex. 340, p. 823, and toxicity can cause nausea, vomiting, headaches, diarrhea, tachycardia, seizures and death, Ex. 81, p. 16; Tr. 1163-64, 2084, 3088-89; *see Bocci I*, 158 Or. App. at 523-24. Historically, the need for frequent dosing and a peaks-and-troughs metabolic cycle made theophylline therapy difficult. Ex. 81, pp. iii, 13.

In the late 1970s, Key introduced Theo-Dur, a sustained-release (SR) theophylline. Ex. 8, p. 28; Ex. 81, p. iii, 34. From the late 1970s into the 1990s, Key promoted Theo-Dur as the superior and "*safe*" theophylline that maintained stable serum concentrations in "virtually all patients," avoided toxic peaks and protected against toxicity, and touted its "zero order absorption" and ability to flatten out the "peaks and troughs."[9] Tr. 1609-10, 1672-74.

On October 27, 1990, when he treated Bocci (and when Bocci suffered his brain-damaging seizures), Dr. Edwards did not know that ciprofloxacin ("cipro"), a quinolone antibiotic, could cause a dramatic decrease in theophylline elimination, or that a stat theophylline level should be obtained when patients, who had been on stable standard doses of Theo-Dur for years without problems, presented with nausea and vomiting. Tr. 1319-20. He did not know that such

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8. Saturation kinetics occurs when the enzymes that metabolize a drug become "saturated" so that the body cannot eliminate the drug at a normal rate, and the serum level increases disproportionately, Tr. 3001, 3029-32, which can occur when either the theophylline level gets very high or theophylline metabolism is somehow impaired. Tr. 984.

9. *E.g.*, Ex. 325 (1978 advertisement); Ex. 81 (May 1979 symposium); Ex. 80 (May 1985 advertisement describing Theo-Dur as unparalleled); Ex. 327 (1987 promotional materials); Ex. 307 (1987 promotional materials, including Dear Doctor letters); Ex. 326 (Theo-Dur 1988 promotional materials); Ex. 162 (1988 Dear Pharmacist letter); Ex. 23, p. 003391 (September 1989 promotional materials).

patients could get into emergency situations or suffer seizures absent a massive overdose.[10]

Key, however, had known these things for years. By 1979, Key knew that saturation kinetics could significantly elevate patients' theophylline levels and cause toxicity. Ex. 81, pp. 26, 48: Ex. 340, p. 823. Key's own vice president of sales and marketing thought that a stat level should be obtained for theophylline patients presenting with nausea and vomiting. CR 205, p. 12; *see* Tr. 1049-50.

In 1982, Key learned that Dr. Ellis, a previous Theo-Dur supporter, *see* Ex. 81, pp. 13-14, had expressed grave concerns about all SR theophylline products. *See* Ex. 304. In a November 1982 internal memo, Key reported that Dr. Ellis had become concerned about "the variable behavior of sustained release theophylline products," was convinced that none was "zero order," and had reported "children having [irreparable] seizures at serum levels of 18 and 19 mcg/ml [that] have turned these children into vegetables," and that he had been "asked to consult on a number of theophylline induced seizure cases." Ex. 304, pp. 1-2. Despite Dr. Ellis' reports of brain damaging seizures, Key chose not to warn, but instead continued to follow the advice of Dr. Weinberger[11] to promote Theo-Dur aggressively.[12]

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10. Tr. 1347-49, 1449-50, 1485-86, 1490-91, 1555. The way Key promoted Theo-Dur was a substantial factor in Dr. Edwards' understanding of the drug's safety and efficacy, Tr. 1549-50, 1552-54, and led him to believe that it was safe and benign on stable, conventional doses, with only mild transient side effects, Tr. 1348-49, 1550, 1553-54, 3800, and that seizures were associated only with massive overdoses, Tr. 1545-50, 3641. Dr. Edwards was not alone in those perceptions of Theo-Dur. *See* Tr. 515, 523-24, 542-43, 555, 1820-21, 2068-69, 2075-76, 2103-04, 2492, 2512-14, 2517-18, 2693-96.

11. Dr. Weinberger served on a panel advising the FDA about regulation of asthma medications. In 1984, it was publicly disclosed that he was a consultant to and had stock options in Key. Tr. 2682-86, 3378-79.

12. *See* Exs. 83, 87, 333; Tr. 2834, 2837. In 1981, Dr. Weinberger had advised Key to use advertising to deliver the "educational message"

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In 1983, the FDA told Key that it had not demonstrated Theo-Dur's clinical superiority because of zero order kinetics, and that such claims were not permitted in the absence of comparative clinical data. Ex. 328. There is no evidence that Key ever performed such clinical studies, even after this admonition and Dr. Ellis' reports. Instead Key's promotional materials continued to extol Theo-Dur's safety and zero order absorption. In February 1987, the FDA again objected to Key's claims in "Dear Doctor" letters and other promotional materials that Theo-Dur was superior to other theophylline products, and told Key to stop using a promotional video that made misleading claims, including a claim that treatment failures were directly attributable to substituting other products for Theo-Dur. *See* Ex. 3, Opp. App. 10a, 12a. Despite these admonitions, Key continued to heavily promote Theo-Dur as the only theophylline having zero-order absorption, and as maintaining stable therapeutic serum concentrations.[13]

An October 1987 internal memo shows that Key knew that "[d]uring the last couple of years there has been increasing documentation of the interaction between quinolone antibiotics [including cipro] and theophylline," causing a decrease in theophylline clearance, and a 44% increase in blood levels. Ex. 11. Despite knowledge that this information was important to practicing physicians,[14] Key did not disclose it and continued

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that Theo-Dur, Key's "current major asset," had an advantage over other slow release formulations. Ex. 87. In 1982, he told Key that, while "[t]he image of theophylline as an effective drug for chronic asthma is taking hold," its image "as a drug that can be administered without adverse effects is not," and urged Key to aggressively address what he characterized as "an important educational message" that "the frequency of adverse effects is less than with oral sympathomimetics." Ex. 83.

13. Ex. 307, pp. 001774, 001778, 001784, 001786, 001791; Ex. 326; Ex. 327, p. 001819; Ex. 337.

14. Ex. 15, p. 000027; Ex. 16, p. 000005; Tr. 853-55; CR 204, pp. 5, 8. Key knew that quinolones were likely to be prescribed for respiratory tract infections common among asthmatics. Ex. 11, p. 000123.

to promote Theo-Dur as safe.[15] Key also failed to report the quinolone antibiotic information to the FDA within 15 days of discovery, as it was required to do. 21 C.F.R. §§ 314.80(b) and (c)(1); Tr. 839-42. In March 1988, Key suggested to the FDA adding quinolones to the list of drugs that could interact to cause stabilized theophylline patients to potentially become toxic, Ex. 13, but failed to submit a proper amended application to do so to the appropriate division of the FDA, Exs. 14, 15; Tr. 818-25, and had to submit another application. Ex. 16; *see* Ex. 18.

Although the FDA told Key in March 1989 that it could add the cipro interaction at the next printing, Ex. 19; Tr. 825-26, Key did not make the PDR deadline, and the 1990 main volume of the PDR did not contain that interaction,[16] Ex. 43; *see* Tr. 845-46. Key could have notified, and no regulation would have prevented it from notifying, the medical community of the interaction at the time it submitted its application. Tr. 818-22. Although Key had told the FDA in June 1988 that the information was important and needed to be disseminated to the medical community as soon as possible, Exs. 15, 16, Key continued to send out promotional materials, *e.g.*, Exs. 6, 22-25; Tr. 835-39, 1647, without disclosing the cipro interaction, and did nothing to warn the medical community except to amend the package insert more than a year later.[17] Exs. 308, 318.

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15. *See* Ex. 326, p. 003193-94; Ex. 302, p. 003440; Ex. 6, pp. 003157, 003174.

16. The interaction was first included in the May 1990 PDR supplement. Ex. 318.

17. Key ultimately revised its package insert to add cipro to the list of drugs with which Theo-Dur could interact at the end of October 1989. Ex. 308. Key did not attach its amended October 1989 package insert to a promotion piece until June 1990, almost 15 months after the FDA approved adding the cipro warning. Tr. 1647-50; Ex. 26. Key took no other steps to inform physicians of the potential danger before October 27, 1990, and did not send any letters to physicians or have any sales or marketing campaign to inform doctors about the interaction and its dangers. Tr. 854-55, 1616-18; CR 205, p. 17.

The only "warnings" Key ever issued relating to Theo-Dur before October 27, 1990 by means other than its package insert were 1988 promotional items cautioning that prescribing or dispensing generic products *instead* of Theo-Dur could put patients at risk of toxicity. Ex. 6. The giving of those "warnings" reflected Key's major concern that it stood to lose $35,000,000 in Theo-Dur sales to generics in 1988 alone. Ex. 28; CR 205, p. 13. Even when the amended package insert adding cipro to the interaction list was finally printed in the May 1990 PDR supplement, it still provided no warning about the need to obtain stat blood levels, or the risk of death or brain-damaging seizures, for patients on stable doses of Theo-Dur who present with gastrointestinal symptoms. Tr. 1066, 1112-13, 1369-70, 1556.

Before October 1990, Key also had access to and knew of literature, summarizing thousands of theophylline toxicity cases (including a number of fatalities), reporting clinical toxicity as a "distressing[ly] common problem," Tr. 861-62, and stating that "[m]any clinicians may not be cognizant of continued reports of severe side effects that result in devastating harm to the patient." Ex. 306, p. 241; Tr. 857-59; CR 204, pp. 11-12. Yet, rather than warn physicians, Key persisted in falsely extolling Theo-Dur's purported "zero order absorption," superiority and safety into 1991, years after learning that such claims were at a minimum suspect and years after the FDA told it to stop.

In January 1989, the FDA issued a Notice of Adverse Findings, Ex. 3, Opp. App. 10a-16a, stating that Key had been employing claims of superiority that the FDA had previously described as "false and/or misleading," as well as "new false and/or misleading claims," "by a variety of promotional vehicles." Ex. 3, Opp. App. 9a-16a. The FDA concluded:

> . . . [Y]our firm has disseminated false and misleading labeling, which causes THEO-DUR to be misbranded . . . .
>
> . . . [Y]our firm has disseminated advertisements which cause THEO-DUR to be misbranded . . . due

> to the absence in such advertisements of a brief summary of side effects, contraindications, and effectiveness. . . .
>
> * * *
>
> Agency experts rejected your firm's request to describe the product's absorption as "zero-order" in the product's labeling. We consider this claim false and/or misleading. . . .
>
> * * *
>
> Your firm has employed falsehoods, misrepresentations, and innuendo, on a continuing basis and in the absence of any valid scientific data, in an effort to convince the medical and pharmaceutical communities that THEO-DUR is superior to all alternative controlled-release theophylline products. We have communicated such concerns in this regard to your firm previously.

Id. The FDA warned Key that misbranded products were subject to seizure and told it to "immediately cease promotion of THEO-DUR as discussed above." Ex. 3, Opp. App. 15a. Even then, Key did not tell its detailers to stop marketing zero order absorption, as the detailer assigned to Dr. Edwards continued to so market Theo-Dur through 1990. Tr. 1665-66. Even after February 1989, the FDA continued to criticize Key for making unfounded superiority claims for Theo-Dur. *See* Ex. 301.

Given Theo-Dur's potential for causing brain damaging seizures and death, and Key's false claims of Theo-Dur's safety and zero order absorption, it was likely at all times that serious harm would arise from Key's failure to warn patients and physicians, including Dr. Edwards, of Theo-Dur's potential dangers. There was ample evidence that strong medicine was needed to get Key's attention,[18] and that warranted a rational

18. As this Court noted in *BMW*, 517 U.S. at 576-77: "Certainly, evidence that a defendant has repeatedly engaged in prohibited conduct while knowing or suspecting that it was unlawful would provide relevant support for an argument that strong medicine is required to cure the defendant's disrespect for the law."

jury to, as the trial court put it, Opp. App. 6a, "assess an amount of punitive damages that would get defendants' attention in a way that the FDA had been unable to achieve for years." Key was long aware of Theo-Dur's dangers and that its claims of Theo-Dur's superiority, safety, and zero order absorption were misleading. Yet, Key continued to engage in false and misleading promotion of Theo-Dur for years after it had knowledge that its claims were seriously questioned, for years after the FDA expressed its disapproval, and even for years (through its detailers) after the FDA issued its Notice of Adverse Findings. Through its intense false and misleading promotional campaign, Key successfully convinced physicians, including Dr. Edwards, that conventional stable doses of Theo-Dur were safe and would produce no more than mild, transient side effects.[19]

Thus, when Bocci, after taking cipro prescribed elsewhere for a skin rash for several days, presented to The Eugene Clinic in October 1990 with symptoms of nausea, vomiting and diarrhea and saw Dr. Edwards, and Dr. Edwards learned that Bocci had been on a stable dose of Theo-Dur for a long time, Dr. Edwards did not diagnose theophylline toxicity, but instead diagnosed and treated Bocci for gastroenteritis and sent him home.[20] Several hours later, Bocci experienced violent seizures and was taken to the emergency room where ultimately, as a "long shot" and an "act of desperation," his theophylline level was checked and theophylline toxicity was diagnosed and treated.[21] Bocci, however, was left with permanent, severely disabling brain damage. Tr. 490, 506-07, 514, 542-43. Dr. Edwards also suffered damage, injury to his reputation and accompanying emotional distress.[22]

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19. Tr. 523-24, 1318-19, 1348-49, 1549-50, 1553-54, 2068-69, 2075-76; *see also* Tr. 1820-21.

20. Tr. 491-92, 1270-71, 1287-93, 1346-51, 1461, 1485-86, 1490-91, 1497, 1500-01; Ex. 39.

21. Tr. 491-94, 496-99, 500-01, 505, 507, 556, 561-62.

22. The evidence concerning Dr. Edwards' damages was not so limited as Key describes, Pet. at 4-5, nor were his damages limited to

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B. Key's Failure to Show That It Raised the Federal Questions Presented in the Courts Below.

Under Rules 14.1(g) and 14.4, Key's failure to include in its statement of the case "a specification of the stage in the proceedings, both in the court of first instance and in the appellate courts, when the federal questions sought to be reviewed were raised," and how they were raised and passed on by those courts, with specific references to the record, is sufficient reason to deny the Petition.

In its "Questions Presented," the first federal question Key posits regarding Dr. Edwards' punitive damages award is whether it is unconstitutionally excessive because "it is cumulative to a $35 million punitive damages award to the injured patient, imposed by the same jury, against the same defendant, to punish and deter the same course of conduct." Yet, although Key purports to show where it raised the federal questions sought to be reviewed in the Oregon courts below, Pet. at 7-8, Key's statement of the case is devoid of any citation

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"at best, only modest emotional distress," as Key asserts, Petition at 16. Dr. Edwards was very concerned and visited Bocci in the hospital after learning of Bocci's seizures and was initially relieved when it seemed Bocci would be all right. Tr. 2548-49. He later learned, however, that Bocci had suffered permanent brain damage and was suing him for malpractice. Tr. 1371, 2550. Dr. Edwards' colleagues saw the lawsuit reported in the papers, and people, aware of the case, asked Dr. Edwards about it. Tr. 2912, 2914, 2916. Dr. Edwards became concerned about how other doctors might view him, Tr. 2553-54, considered quitting the practice of medicine, Tr. 1372, became insecure with his medical knowledge, relied more heavily on specialists, referred patients to other physicians more often, and ordered more tests, Tr. 3650. He became concerned about reporting to the National Practitioner Data Bank and the effect of Bocci's case on his professional reputation, Tr. 2554, 2913, and, when the opportunity to move arose, he decided to leave Oregon and seek a fresh start. Tr. 1372, 2555-56. He also experienced intestinal discomfort (diarrhea, cramping and bloody stools) so severe that Crohn's disease was suspected. Tr. 2551-53.

to any place in the Oregon trial and appellate court records where its first federal question was raised.

The second federal question Key posits regarding Dr. Edwards' punitive damages award is whether it is unconstitutionally excessive because purportedly "the jury was permitted to impose each award [Bocci and Dr. Edwards' awards] as punishment for all of the harm actually or potentially caused throughout the United States by petitioner's conduct of a national marketing campaign." Although Key properly notes that the Oregon Court of Appeals in *Bocci II* rejected that argument,[23] Pet. at 10, Key fails to cite to any place in the trial court record where it raised that specific question, or where it sought to exclude evidence of its national marketing campaign or sought to limit, by instruction or otherwise, the jury's ability to consider such evidence in deciding punitive damages. Moreover, as Key notes, Pet. at 6, "[n]either Plaintiff nor Dr. Edwards presented evidence of any other injury caused by Key's marketing of Theo-Dur."

Key has also failed to show when in the Oregon appellate courts Key pressed the federal constitutional question it posits in its "Questions Presented" concerning the Mary Carter

23. As the Court of Appeals explained in *Bocci II*, 178 Or. App. at 49, Pet. App. 8a:

> . . . Key argues that its misleading marketing of Theo-Dur was part of a nationwide campaign and that the State of Oregon lacks any legitimate state interest in punishing its conduct outside of Oregon. We rejected a similar argument in *Axen v. American Home Products Corp.*, 158 Or. App. 292, 315, 974 P.2d 224, *adhered to on recons.* 160 Or. App. 19, 981 P.2d 340, *rev. den.* 329 Or. 357, 994 P.2d 124 (1999), *cert. den.* 528 U.S. 1136 . . . (2000). That case, like this one, concerned a punitive damage award involving misleading promotion of a prescription drug that led to damages to an Oregon plaintiff. In *Axen*, we held that the defendant 'was not punished for its promotional activities outside of Oregon — it was punished for failing to warn [the Oregon plaintiffs'] physicians' of a potential hazard of the drug involved. *Id.* at 315, 974 P.2d 224.

agreement.[24] Although Key asserts that it sufficiently preserved at trial and on appeal a federal question whether the trial court's handling of the Mary Carter Agreement deprived Key of its right to due process of law, Key cites only some sentences from its 26-page pre-trial Motion to Dismiss, or in the Alternative, to Have the Mary Carter Agreement Declared Void, Pet. App. 77a. *See* Pet. at 7-8 and n. 6. Even if Key preserved such a question in the trial court simply by asserting in a motion filed two months before trial that "Mary Carter Agreements create a trial environment which is so unfair to the nonsettling defendants as to deprive them of their constitutional right to a fair trial" and that the "Due Process Clause of the Fourteenth Amendment guarantees litigants a fair trial," Key cites no place where it argued in the Oregon appellate courts that the Mary Carter agreement or its handling in the trial court violated Key's constitutional due process rights.[25] Indeed, the only arguments by Key relating to the Mary Carter agreement which the Oregon Court of Appeals addressed in *Bocci I*, 158 Or. App. at 527-39, Pet. App. 19a-34a, were arguments concerning the validity and procedural handling of the Mary Carter agreement under Oregon, not federal, law.

REASONS FOR DENYING THE PETITION

Key's Petition should be denied, not only because of its failure to fully comply with Rules 14.1(g) and 14.4, but also because the questions Key presents are premised upon a distorted presentation of the facts and record below and upon arguments and objections that were neither pressed nor passed upon below, and because there are no compelling reasons warranting review by this Court.

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24. Key erroneously asserts, Pet. at 3, that Bocci and Dr. Edwards entered into the "Covenant Not to Enforce Judgment and Separate Loan Agreement," before Bocci filed this lawsuit. The signed agreement is undated, but the record shows that the lawsuit was filed on October 12, 1992, and that the agreement was not signed until the last week of October or the first two weeks of November 1992. Tr. 24-25, 1379-80.

25. What Key cites and quotes, Pet. at 8 n.7, from its opening appellate brief does not show that it raised on appeal a federal due process issue with respect to the agreement. *See* Pet. App. 97a.

The question Key presents as to the constitutionality of Dr. Edwards' punitive damage award is predicated upon three objections: (1) that the award is cumulative to Bocci's $35 million award, imposed by the same jury, against the same defendant, to punish and deter the same conduct; (2) that the jury was permitted to impose each award for all of the harm actually or potentially caused throughout the United States by Key's conduct of a national marketing campaign; and (3) that the appellate court relied upon a "rational juror" standard of review that is somehow contrary to the due process requirements articulated by this Court in *Oberg* and *BMW*. All three predicate objections are unfounded.

The first objection was not raised by Key in either the trial or the appellate courts below, and thus was not passed upon by the Oregon Court of Appeals in either *Bocci I* or *Bocci II*. The second objection, rejected by the Oregon Court of Appeals, *see* footnote 23, *supra*, was not raised in the trial court, and is factually incorrect. The third objection is both factually and legally incorrect and premised upon a distortion of Oregon's "rational juror" standard.[26]

The question Key presents as to the constitutionality of the Mary Carter agreement and its procedural handling by the trial

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26. Moreover, the third objection draws into question the constitutionality of Or. Rev. Stat. § 18.537(2) (1995), a statute which became effective after the trial in this case, and which provides that:

> If an award of punitive damages is made by a jury, the court shall review the award to determine whether the award is within the range of damages that a rational juror would be entitled to award based on the record as a whole, viewing the statutory and common-law factors that allow an award of punitive damages for the specific type of claim at issue in the proceeding.

Opp. App. 9a. Key, however, has failed to comply with Rule 29.4(c), which requires that:

> In any proceeding in this Court in which the constitutionality of any statute of a State is drawn into question, and neither the State nor any agency, officer, or employee thereof is a party, the initial document filed in this Court shall recite that 28 U.S.C. § 2403(b) may apply and shall be served on the Attorney General of that State.

court also was neither pressed below[27] nor passed upon by the Oregon Court of Appeals. The challenges Key made on appeal to the Mary Carter agreement and its procedural handling in the trial court were all based upon, and decided according to, state law, and involved no presentation of any federal question subject to review by this Court. Such state law issues fall outside the jurisdiction of this Court. *E.g.*, *Murdock v. Memphis*, 87 U.S. 590, 632-33 (1875).

The Oregon Court of Appeals did not decide any important question of federal law in a way that conflicts with any decision of this Court, nor did it decide any new federal question that has not been, but should be, decided by this Court. To the contrary, the Oregon Court of Appeals in *Bocci II* properly applied this Court's decisions in *Cooper Industries*, *BMW*, and *Oberg*, conducted a *de novo* review of the punitive damages award in light of the arguments made by Key that were properly preserved, the facts as the jury was entitled to find them, and the *BMW* guideposts, and affirmed the punitive damage award. *Bocci II*, Pet App. 1a-11a. The Oregon Court of Appeals' rejection in *Bocci I*, 158 Or. App. at 527-39, Pet. App. 19a-34a, of Key's state law challenges to the Mary Carter agreement and the trial court's procedural handling of it, does not give rise to any federal constitutional due process question that needs to be decided by this court.

Finally, although Key has torturously tried to recast its issues to make them appear to resemble issues presented in *State Farm Mut. Auto. Ins. Co. v. Campbell*, No. 01-1289 (*cert. granted* June 3, 2002)), the issues preserved and passed on below bear no resemblance to the issues involved in *State Farm*. There is no reason to withhold action on Key's petition pending a decision in *State Farm*.

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27. Many of Key's specific Mary Carter-related challenges were not even adequately preserved in the trial court.

A. Contrary to Key's Assertion, This Case Does Not Present Important Federal Questions Regarding Application of This Court's Decisions to Multiple Punitive Damages Awards Based Upon Nationwide Conduct.

Contrary to Key's assertions, Pet. at 15-16, this case is not "a case where a defendant has been subjected to multiple punitive damages awards for the same conduct," nor is it an appropriate vehicle for this Court to address the issue Key posits of "whether the due process clause allows states to use punitive civil damages to inflict multiple monetary punishments for the same offense."

First, Key did not raise that issue below and thus the Oregon courts did not pass upon it. Generally, this Court will not review a federal law issue arising out of state court litigation that was not pressed or passed on below. *E.g.*, *TXO Prod. Corp. v. Alliance Resources Corp.*, 509 U.S. 443, 463-64 (1993); *Illinois v. Gates*, 462 U.S. 213, 217-23 (1983).

Second, this case is not now nor has it ever been about "multiple monetary punishments" or "cumulative" punitive damages awards. There is no evidence in this case that Key has received multiple punishments for the same conduct that gave rise to the punitive damages awarded in this case, or that anyone other than Bocci or Dr. Edwards has sued Key for the same conduct. As the trial court noted, Opp. App. 5a, "[d]efendants offered no evidence in this case that they had received 'other punishment' as a result of proceedings similar to this case."

Key's speculative assertion, Pet. at 14, that it faces "a very substantial risk of multiple, redundant, and excessive punishment" because it markets products nationwide hardly makes this case an appropriate vehicle to address an issue that was not raised or briefed in the courts below. If Key had evidence of actual or potential multiple punishments, it could and should have offered it at trial under Or. Rev. Stat. § 30.925(3)(g), which authorizes the jury and the reviewing court to consider "[t]he total deterrent effect of other punishment imposed upon the defendant as a result of the misconduct, including, but not

limited to, punitive damage awards to persons in situations similar to the claimant's . . ."

Moreover, although Key complains, Pet. at 15, that "[h]ere, a single jury, in a single case, awarded punitive damages to two different claimants, for the exact same conduct," Key cites no authority that suggests that allowing a jury to award punitive damages in a single case to each of two claimants who were both injured by the defendant's reprehensible conduct gives rise to a due process concern over multiple punishments for the same conduct.[28] Indeed, even Key acknowledges, that "historically, punitive damages typically were awarded in cases involving harm to one *or a few* individuals."[29] Pet. at 14 (emphasis added). In this case, Key is no longer even subject to two punitive damages awards or punishments, as Bocci's judgment was vacated after Key settled with Bocci on appeal.

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28. Key suggests, Pet. at 15 and n.12, that Oregon's statutory entitlement to a portion of the punitive damages awards implicates the Eighth Amendment excessive fines clause. Yet, at no time did Key ever raise any such issue in the appellate courts below.

29. Key also complains, Pet. at 18-19, that the trial court gave the jury two special verdict forms, one asking what Bocci's punitive damages were and the other asking what Dr. Edwards' punitive damages were, and each having a blank space to fill in the award and an instruction that the award could not exceed $35 million. Key, however, did not except at trial to the special verdict forms on those bases and did not assign error or argue on appeal that the special verdict forms somehow permitted an impermissible multiplicity of awards. Under Oregon law, an appellate court will not consider objections to jury instructions or special verdict forms to which exceptions were not made at trial, *Berhanu v. Metzger*, 119 Or. App. 175, 177, 850 P.2d 373, *rev. denied*, 318 Or. 60 (1993), *cert. denied*, 511 U.S. 1106 (1994), and an exception on one ground does not preserve error on another ground. *Propp v. Long*, 129 Or. App. 273, 277, 879 P.2d 187, *rev. denied*, 320 Or. 271, 277 (1994). Moreover, in order to have an Oregon appellate court consider an issue, it must be assigned as error. Or. Rule App. Proc. 5.45(2); *Lutz v. State By and Through Carey*, 130 Or. App. 278, 283, 881 P.2d 171 (1994).

1. The Oregon courts did not impermissibly permit disproportional and cumulative punitive damages awards.

In *BMW*, 517 U.S. at 568, this Court held that review of a punitive damages award for gross excessiveness begins with identification of the state interests that a punitive damages award is designed to serve. This Court then identified three "guideposts" courts are to consider when evaluating whether a defendant has received fair notice of the magnitude of the punitive damages award that might be imposed: (1) the degree of reprehensibility of the defendant's conduct; (2) the disparity between the punitive damages award and the actual or potential harm inflicted; and (3) the civil and criminal sanctions provided for comparable misconduct. *Id.* at 574-85. In its Petition Key completely ignores the first guidepost ("the degree of reprehensibility"), ever though the *BMW* court made clear that it is "[p]erhaps the most important indicium of the reasonableness of a punitive damages award." *Id.* at 575.

Key asserts, Pet. at 20, that Dr. Edwards' punitive damages award "is not justified by Oregon's legitimate interest in punishment and deterrence of wrongful conduct." While Key's assertion is not all that surprising given Key's erroneous view that its conduct was not all that wrongful, it cannot seriously be contended that Dr. Edwards' punitive damage award does not advance legitimate and proper state interests. As the court in *Axen v. American Home Prods. Corp.*, 158 Or. App. 292, 319-20, 974 P.2d 224, *adhered to as modified*, 160 Or. App. 19, 981 P.2d 340, *rev. denied*, 329 Or. 357 (1999), *cert. denied*, 528 U.S. 1136 (2000), explained, Oregon has an interest "in protecting Oregon residents against harm caused by the failure to give them and their physicians adequate warning of the dangerous side effects of prescription drugs," "in avoiding the costs of providing health care to patients harmed by mislabeled medications," and "in preventing the loss of productive members of society." As the court further explained in *Bocci II*, 178 Or. App. at 49, Pet. App. 8a-9a: "The state's interests are identical, whether the harmed party receiving the award is a patient or a physician."

Contrary to Key's insistence, Pet. at 20, that trial and appellate courts must focus on the ratio of a given plaintiff's punitive damages to that plaintiff's actual damages, this Court has "consistently rejected the notion that the constitutional line is marked by a simple mathematical formula, even one that compares actual *and potential* damages to the punitive award." *BMW*, 517 U.S. at 582.

> [B]oth State Supreme Courts and this Court have eschewed an approach that concentrates entirely on the relationship between actual and punitive damages. It is appropriate to consider the magnitude of the *potential harm* that the defendant's conduct would have caused to its intended victim if the wrongful plan had succeeded, as well as the possible harm to other victims that might have resulted if similar future behavior were not deterred.

TXO, 509 U.S. at 460 (emphasis in original). Thus, the proper inquiry under the second *BMW* guidepost is "whether there is a reasonable relationship between the punitive damages award and *the harm likely to result* from the defendant's conduct as well as the harm that has actually occurred." *BMW*, 517 U.S. at 581 (quoting *TXO*, 509 U.S. at 460, and *Pacific Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1, 21 (1991) (emphasis in original).

Contrary to Key's argument, Pet. at 17, the Oregon Court of Appeals, when it declined to review Dr. Edwards' punitive damage award independently of Bocci's award under the second *BMW* guidepost, was not unwilling to probe the basis of the jury's verdict; it was unwilling to review an issue that Key had failed to preserve and in fact had waived. *See Bocci I*, 158 Or. App. at 773, Pet. App. 46a. As the Court explained in *Bocci II*, 178 Or. App. at 51, Pet. App. 11a, Key failed to preserve in the trial court the issue that the ratio of punitive damages awarded to Dr. Edwards to the compensatory damages awarded to Edwards is excessive, having "argued only that the *total* award

to Bocci and Edwards was excessive."[30] The court further observed that "[n]othing in *Cooper Industries* suggests that appellate courts are required to consider unpreserved issues." *Id.*

The Court of Appeals was not wrong in concluding that Key failed to preserve the issue. In its post-trial motions, Key asked the trial court to "declare the entire amount of the punitive damages awarded to Plaintiff and Dr. Edwards excessive." Preceding the excerpt from its reply on post-trial motions that Key quotes in its Petition at page 9,[31] Key argued that:

> In their Responses, Plaintiff and Dr. Edwards deal separately with their respective punitive damage awards. However, this Court must consider aggregating the punitive damage awards to determine whether, in combination, they exceed the maximum amount tolerable under the Due Process Clause because both awards are premised on the same factual basis and because the jury had before it all of the evidence pertaining to the totality of the wrongful conduct sought to be punished. . . .[32]

Even if Key had preserved the argument, nothing in this Court's decisions limits the proportionality review to whether there is a reasonable relationship between Dr. Edwards' punitive damages and his actual damages, or requires the reviewing court to ignore actual or potential harm to others.

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30. The court noted that the ratio of the combined punitive to compensatory awards was roughly 10:1. *Id.* at 51 n.3, Pet. App. 11a.

31. That excerpted quote appears nowhere in Key's opening appellate brief, its Appendix, its appellate reply brief, or its reply Appendix, notwithstanding the requirements of Or. Rule App. Proc. 5.45(4), which, at the time Key's briefs were filed, provided that "Each assignment of error . . . must set out verbatim the pertinent portions of the record, if it relates to a specific ruling that is being challenged."

32. Even after Key's quoted excerpt, Key stated: "Given the lack of any substantial evidence supporting the factors set out in ORS 30.925(3), the combined punitive damage awards of $57.5 million were clearly contrary to the weight of the evidence and should be remitted . . ."

Key argues that a comparison of the punitive damage to compensatory damage ratios of the awards to Bocci and Dr. Edwards shows how grossly disproportionate Dr. Edwards' award is. *See* Pet. at 16. Key, however, ignores that the jury, instructed that it could not award Bocci more than $35 million in punitive damages, awarded Bocci the maximum amount it could. Pet. App. 124a. Any comparative disproportion between the proportion of Bocci's punitive damages to his actual damages, and the proportion of Dr. Edwards' punitive damages to his actual damages, is likely due to the fact that the jury was constrained by the court's instruction not to award Bocci any more than $35 million.

2. The Oregon courts did not impermissibly rely upon out of state conduct to justify the punitive damages awards.

Contrary to Key's assertion, Pet. at 20, this case presents no issue concerning "states imposing punitive damages for consequences outside their borders." As even Key has acknowledged: "Neither Plaintiff nor Dr. Edwards presented evidence of any other injury caused by Key's marketing of Theo-Dur." Nor is this case like *BMW* where the jury's verdict reflected an amount of punitive damages "based in large part on conduct that happened in other jurisdictions" but that was *lawful* in those other jurisdictions. *See BMW*, 517 U.S. at 572-73.

Just because Key's reprehensible conduct occurred as part of a long-term nationwide marketing campaign does not mean that the jury's punitive damage award impermissibly punished Key for out-of-state conduct.[33] Indeed, the Oregon Court of

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33. Key's argument in this regard, if accepted, would mean that individuals or entities who engage in reprehensible misconduct as part of nationwide campaigns would be insulated from the deterrent effect of significant punitive damages awards in any one state where proven injury occurred, because the possibility exists that many more people in many other states might sustain similar injuries as a result of the same

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Appeals explicitly rejected such an assertion, quoting with approval the holding in *Axen*, *supra*, 158 Or. App. at 315, that the defendant before it "'was not punished for its promotional activities outside of Oregon — it was punished for failing to warn [the Oregon plaintiffs'] physicians' of a potential hazard of the drug involved." *Bocci II*, 178 Or. App at 49, Pet. App. 8a.

Consideration of the profitability of Key's misconduct does not mean that Key was being punished for out-of-state conduct. Key's profit motive is certainly relevant to the degree of reprehensibility of its misconduct, and the profitability of Key's conduct is one of the statutory factors in Oregon to be considered in assessing punitive damages. Consideration of Key's "gargantuan size"[34] also does not mean that Key was being punished for extraterritorial conduct. *See* Pet. at 21-22. Indeed, this Court, in *TXO*, 509 U.S. 462 n. 28, rejected contentions that admission of evidence of defendant's alleged wrongdoing in other parts of the country and of defendant's "impressive net worth" allowed the jury to base its award on impermissible passion and prejudice, stating: "Under well-settled law, . . . factors such as these are typically considered in assessing punitive damages."

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reprehensible wrongful conduct. If accepted, such an argument would result in the absurdity that, because Key engaged in such reprehensible misconduct with so much potential for severe harm to so many potential victims nationwide, Key should be subjected to lesser, not greater, punitive damages.

34. Key asserts, Pet. at 22, that the trial court's "emphasis on Key's 'gargantuan size,' without connecting that size in any way to its market share in Oregon," reflects punishment for out-of-state behavior. Key's argument, besides being wrong, ignores the fact that Key chose not to present any evidence of its market share in Oregon or the profitability of its Oregon sales of Theo-Dur. As the court noted in its Opinion Denying Post-Trial Motions: "Defendants made the tactical choice to present no financial data for the jury to consider in assessing punitive damages; thus the range of alternative measurements is limited." Opp. App. 3a.

3. Oregon's "rational juror" inquiry is not in conflict with this Court's decisions in *Oberg*, *TXO*, *BMW*, or *Cooper Industries*.

Key's assertions, Pet. at 22-26, that Oregon's "rational juror" standard of review is somehow inconsistent with the standards of *de novo* review identified by this Court, are factually and legally incorrect and premised upon a distortion of Oregon's "rational juror" inquiry. Contrary to Key's assertion, Pet. at 23, Oregon's "rational juror" standard is not simply a "sufficiency of the evidence standard" under which "a jury's punitive damages verdict would not be disturbed so long as there was any evidence to support it."

In holding that "the rational juror inquiry remains the standard of post-verdict review of punitive damages in Oregon for excessiveness," the Oregon Supreme Court in *Parrott*, 331 Or. at 554, Pet. App. 153a-154a, explained that: (1) "the rational juror inquiry is merely one of the 'different formulations' of the 'grossly excessive' standard adopted by the Supreme Court;" (2) "the rational juror standard is compatible with and does not differ practically from [*BMW v.*] *Gore's* gross excessiveness inquiry;" and (3) "[*BMW v.*] *Gore* has not 'superceded' the rational juror standard that this court articulated in *Oberg* (state)." Moreover, as the Oregon Court of Appeals in *Bocci II*, 178 Or. App. at 51, Pet. App. 10a, correctly pointed out, "[n]othing in *Cooper Industries* calls into question the 'rational juror' standard of review announced by the Oregon Supreme Court in *Oberg*."

Oregon's "rational juror" standard is not, as Key implies, Pet. at 24, akin to the "rational basis" standard (the standard of review for state economic legislation) advocated in *TXO*, 509 U.S. at 455-56, that would have rendered acceptable "*any* award that would serve the legitimate state interest in deterring or punishing wrongful conduct, no matter how large." A punitive damage award that does not sufficiently satisfy the Oregon statutory and common law factors that allow for an award of punitive damages in a given type of case, or that does not

comport with a legitimate state interest or the *BMW* guideposts, would not be within the range that a rational juror could award and would not survive Oregon's "rational juror" inquiry.

Contrary to Key's assertions, Pet. at 25, the Oregon appellate courts have not ignored the teachings of this Court in *BMW* and *Cooper Industries* or left punitive damages "to the sole unfettered discretion of the judge and jury." To the contrary, the Oregon Court of Appeals in *Bocci II* conducted a *de novo* review in light of: (1) the Oregon Supreme Court's decision in *Parrott*; (2) this Court's decisions in *Cooper Industries*, *BMW*, and *Oberg*, including the *BMW* guideposts; (3) the arguments of Key that were properly preserved; and (4) the facts as the jury was entitled to find them,[35] and determined that Dr. Edwards' punitive damages award was not grossly excessive or unconstitutional.

B. This Case Does Not Present A Federal Question Concerning Mary Carter Agreements.

Key asserts, Pet. at 26-27, that the Mary Carter agreement and the trial court's handling of it deprived Key of due process of law under the Fourteenth Amendment. Even if Key had pressed that issue below, which it did not, Key's assertion distorts the law and record, and is meritless. Neither the Mary Carter agreement[36] nor the trial court's handling of it presents a federal question. If it did, this Court would become a court of last resort for every state law procedural and evidentiary error that an imaginative aggrieved party argues deprived it of a fair trial.

Contrary to Key's assertions, Pet. at 5-6, 26-27, 29, Dr. Edwards was not a "stealth plaintiff" against Key, nor was Key deprived of adequate procedural protections. The jury

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35. Even Key concedes, Pet. at 24, that, under *Cooper Industries*, "a reviewing court must accept the jury's findings of fact unless they are clearly erroneous."

36. Mary Carter agreements are not invalid or against public policy under Oregon law. *Grillo v. Burke's Paint Co.*, 275 Or. 421, 427, 551 P.2d 449 (1976); *Bocci I*, 158 Or. App. at 528-29, Pet. App. 21a.

was not kept in the dark about Dr. Edwards' interest or bias.[37] The trial court told the jury about the agreement, that it contained a schedule for repayment depending on Bocci's recovery against Key, that Dr. Edwards had a financial interest in the outcome of Bocci's claims against Key because it would affect the amount that Dr. Edwards would have to pay, and that Dr. Edwards had his own claims, including a claim for punitive damages, against Key. *See Bocci I*, 158 Or. App. at 532-33, Pet. App. 25a-26a. Key had the opportunity but elected not to propose additional instructions on the agreement. Tr. 139, 150, 1380-81.

Under Oregon law, Key was not entitled to have the agreement admitted into evidence when it contained inadmissible references to Dr. Edwards' liability insurance and to potential settlement amounts (from $200,000 to $1,000,000 depending on the outcome of Bocci's claims against Key).[38] *See Bocci I*, 158 Or. App. at 533-36, Pet. App. 28a-31a. Nor was Key prevented from cross-examining Dr. Edwards about the agreement. The trial court merely sustained an objection when Key essentially repeated a question about financial exposure that had just been asked and answered, and then told Key "no" when Key asked if he could explore it. The record shows in context that Key's questions about financial exposure were aimed at pointing out the settlement amount and

37. Key was not precluded from referring to the agreement in opening, Tr. 148-49, although it was precluded from referring to the payment sequencing and insurance matters, Tr. 336, 437-38, and Key's closing argument about the agreement was unrestricted in the extreme, Tr. 4131-35, 4216-19.

38. Although claiming that the entire agreement should have been admitted, Key argued in the trial court that a redacted form of the agreement (that is not of record) should be admitted, deleting certain recitals, but not deleting the inadmissible references to liability insurance and potential settlement amounts. *Bocci I*, 158 Or. App. at 535-36, Pet. App. 30a-31a. A party who attacks the exclusion of an exhibit that contains some irrelevant material has "the burden of excising the irrelevant portions to preserve the claimed error." *Fazzolari v. Portland School Dist.*, 78 Or. App. 608, 614, 717 P.2d 1210 (1986), *aff'd on other grounds*, 306 Or. 1, 760 P.2d 1317 (1988).

Dr. Edward's insurer's participation. Tr. 89-90, 144-45, 151, 436-37, 2937. *See Bocci I*, 158 Or. App. at 538, Pet. App. 33a. Key made no offer of proof as to what evidence of bias it would have elicited on further cross-examination of Dr. Edwards about the agreement.[39] *See Bocci I*, 158 Or. App. at 536-39, Pet. App. 31a-34a.[40]

The essence of Key's complaints about the agreement is that it somehow rendered the trial unfair because Bocci and Dr. Edwards had a common interest in "pointing the finger" at Key. That interest existed, however, with or without the agreement, because it was Key's theory that Bocci and Dr. Edwards, not Key, were at fault, and because both Bocci and Dr. Edwards had claims against Key. Just as codefendants often cooperate for the shared purpose of defeating the claims of a single plaintiff, a trial in which a plaintiff and co-defendant both "point the finger" at another defendant is neither uncommon or qualitatively less fair. *See Bocci I*, 158 Or. App. at 532, Pet. App. 25a. Key's complaints about the Mary Carter agreement do not present any federal questions so as to warrant this Court's review.

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39. Key's "offer of proof," which Key failed to set forth verbatim until its reply brief did not show what evidence Key would have elicited from Dr. Edwards, but only what arguments Key would have made about the agreement, Tr. 2935-40, most of which would have been impermissible as relating to settlement amount or Dr. Edwards' liability insurer. Nevertheless, Key told the jury in closing argument that Dr. Edwards' payment to Bocci should end the case. Tr. 4217.

40. Key complains that it was not allowed to cross-examine some of Bocci's witnesses to try to establish Dr. Edwards' culpability. Key raised one assignment of error in that regard as to one witness and assigned it as error only as against Bocci, not Dr. Edwards. Thus, the Court of Appeals did not consider that argument. Moreover, Key's questions would have been beyond the scope of direct, and Key had its own physician expert who offered criticism of Dr. Edwards. Tr. 3665-72.

C. The Court Should Not Withhold Action Pending A Decision in *State Farm*.

Key suggests, Pet. at 13, that the Court "may find it appropriate to withhold action" on Key's petition until after the Court's decision in *State Farm Mut. Auto. Ins. Co. v. Campbell*, No. 01-1289. Despite Key's distorted presentation of the issues and record, the issues preserved and passed upon by the Oregon Court of Appeals in this case bear no resemblance to the "Question Presented" in the *State Farm* petition, which is:

> Whether the Utah Supreme Court, in direct contravention of this Court's decision in *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996), and fundamental principles of due process, committed constitutional error by reinstating a $145 million punitive damage award that punishes out-of-state conduct, is 145 times greater than the compensatory damages in that case, and is based upon the defendant's alleged business practices nationwide over a twenty year period, which were unrelated and dissimilar to the conduct by the defendant that gave rise to the plaintiffs' claims?

The Petition in *State Farm* identifies numerous discrete and separate examples of dissimilar and unrelated practices that were admitted into evidence even though, according to State Farm, the plaintiffs made no showing that the practices were unlawful in the states where they were performed.

In contrast, here, while Key's fraudulent promotion of Theo-Dur occurred as part of a long-term nationwide marketing campaign, there was no evidence of dissimilar or unrelated conduct that was *lawful* in other states. Even according to Key, Pet. at 6, there was no evidence introduced by Bocci or Dr. Edwards of other injuries caused by Key's fraudulent promotion. Moreover, Key's misconduct violated FDA regulations and was *unlawful* nationwide.

Finally, whether the 145:1 ratio of punitive to compensatory damages in State Farm is constitutionally acceptable or not is dependent upon the facts of *that* case. The comparison of punitive damages to the actual and potential harm resulting from a defendant's wrongful conduct is necessarily fact-specific, which is why this Court has consistently resisted applying any mathematical formula.

Because this case, which is now roughly eight years out from entry of judgment, bears no resemblance to *State Farm* and does not share the same issues, this Court should not withhold action until *State Farm* is decided.

CONCLUSION

For the foregoing reasons, this Court should deny Key's petition for writ of certiorari.

Respectfully submitted,

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APPENDIX

APPENDIX A — OPINION DENYING POST-TRIAL MOTIONS

IN THE CIRCUIT COURT OF THE STATE OF OREGON

FOR THE COUNTY OF MULTNOMAH

Case No. A9210-07050

PAUL R. BOCCI, JR., Guardian ad Litem for PAUL R. BOCCI, III, an incapacitated individual,

Plaintiff,

v.

KEY PHARMACEUTICALS, INC., a foreign corporation; SCHERING-PLOUGH CORPORATION, a foreign corporation; SCHERING CORPORATION, a foreign corporation; MILES, INC. an Indiana corporation; LEGACY HEALTH SYSTEM, an Oregon corporation; LEGACY IMMEDIATE CARE CLINIC; FREDERICK D. EDWARDS, M.D.; and THE EUGENE CLINIC, a partnership,

Defendants.

FREDERICK D. EDWARDS, M.D.,

Cross-Claim Plaintiff,

v.

KEY PHARMACEUTICALS, INC., a foreign corporation; SCHERING-PLOUGH CORPORATION, a foreign corporation; SCHERING CORPORATION, a foreign corporation,

Cross-Claim Defendants.

Appendix A

OPINION DENYING POST-TRIAL MOTIONS

The defendants' Motions for New Trial, Remittitur, and for Judgment N.O.V. came before me on October 28, 1994. . . .

For the reasons stated below, all of defendants' post-trial motions are *denied*.

* * *

PUNITIVE DAMAGES

The jury in this case assessed punitive damages against defendants in the sum of $57.5 million; $35 million to plaintiff and $22.5 million to Dr. Edwards. With respect to punitive damages, defendants attack the jury's verdict with all barrels. They move for a Judgment N.O.V., contending there was no evidence to prove plaintiff's and Dr. Edward's entitlement to punitive damages; they ask for a Judgment N.O.V. on the basis that punitive damages in Oregon are unconstitutional as a matter of state law; they move for a new trial on the basis of insufficient proof; and in the alternative they ask for a remittitur. All of those motions are *denied*.

* * *

The jury's assessment of punitive damages in the sum of $57.5 million is not "grossly excessive" and does not violate federal due process. The award is entirely reasonable under the facts of this case and is appropriately proportional in relation to the damages caused when compared with defendants' financial condition. A review of the amounts assessed and the standards the jury was instructed to apply shows that there is no basis to order a new trial or to grant a remittitur.

Appendix A

The evidence was that defendants' 1993 sales were approximately $4,300,000,000, and 1993 profits were approximately $1,100,000,000. The punitive damages assessed in this case approximate 5 percent of defendants' 1993 profits, or 1.3 percent of 1993 sales. The jury also heard that the market value of defendants' companies ranges from $10.1-13.9 billion. Assuming a median market value of $12.0 billion, the punitive damages in this case equal .00479% of that 1993 market value. Given the gargantuan size of defendant's companies, it cannot be said that the amount of punitive damages in this case "shocks the conscience" of the court. (Defendants made the tactical choice to present no financial data for the jury to consider in assessing punitive damages; thus the range of alternative measurements is limited.)

Although defendants object to using the financial health of their corporations as a measuring standard, ORS 30.925(3)(f) clearly provides that the "financial condition of the defendant" is one of the criteria upon which punitive damages "shall be determined and awarded."

The jury in this case was asked specifically whether defendants' conduct showed "wanton disregard for the health, safety and welfare of others." They answered in the affirmative. There was evidence in the record to support their decision, not the least of which is Ex. #3 and the pattern of using the FDA labeling process as a shield to try to avoid liability and to delay dissemination to the medical community about the dangers of Theo-Dur and dangers of adverse inter-reactions with other drugs.

The criteria for assessing punitive damages in these kinds of cases are outlined in ORS 30.925(3). I am aware of no statutory interpretation which says that there must be proof of each of the criteria before punitive damages may be awarded. The statute is a descriptive list rather than a mandatory list.

Appendix A

ORS 30.925(3)(a) provides that one criterion is the likelihood that serious harm would arise from defendants' misconduct. Defendants argue that this criterion cannot apply in a prescription drug case because all prescription drugs are dangerous and will cause serious harm if not used according to FDA approved package inserts and the medical advice of a prescribing physician. What is at issue here, however, is defendants' failure to warn the medical community honestly about the dangerousness of Theo-Dur. Plaintiff's brain damage is obviously "serious harm." The jury had evidence from which it reasonably could infer that defendants' failure to inform the FDA and warn the medical community made it likely that harm such as plaintiff's would arise from defendant's misconduct.

ORS 30.925(3)(b) states that another criterion is the "degree of the defendant's awareness of that likelihood." There was evidence from which the jury could infer reasonably that defendants have known for years that their advertising to the medical community was false and misleading. There was evidence from which the jury could infer that, at least by 1987, defendants became aware of the potential for adverse inter-reactions between ciproflaxacin and Theo-Dur, but that defendants engaged in a delaying tactic in the guise of applying to the FDA for "permission" to alter the package insert while taking the position that they could not warn the medical community without approval from the FDA. The jury could infer that this was a deceptive tactic. There was evidence in the case that defendants could have warned the medical community about these dangers immediately and without "permission" from the FDA.

ORS 30.925(3)(d) provides that other criteria are the "duration of the misconduct and any concealment of it." ORS 30.925(3)(e) states that further criteria are the "attitude and conduct of the defendant upon discovery of the misconduct."

The comments made in the previous paragraph about violation of Sec. (3)(b) apply equally here. There was evidence that for eight years defendants had promoted its drug as safe and as having "zero-order absorption," and that they had misled the medical community about the safety of its drug since 1978. There was evidence from which the jury could conclude that defendants have aggressively resisted informing the medical community about adverse reactions, while at the same time aggressively promoting "Dear Pharmacist" letters when possible financial losses might occur as a result of adverse publicity.

ORS 30.925(3)(c) says that another criterion is the "profitability" of the defendants' misconduct. Defendants argue that there was no proof on this point. They assert that statutory "profitability" is limited to the difference between profits actually earned and the lesser profits that would have occurred if additional warnings had been added earlier. They say that plaintiff and Dr. Edwards provided "no evidence regarding the number of sales that would have been lost had those warnings been issued." (Defendants' Motion, p. 50) They argue that such evidence would be speculative. Indeed such evidence would be speculative in the absence of proof. However, defendant did not object at trial that there was no proof that fit this narrow interpretation of the statute. Plaintiff offered evidence about defendants' profits; defendants did not challenge those figures or demand that they be confined within the constraints that they now insist upon.

ORS 30.925(3)(g) provides that another criterion is the "total deterrent effect of other punishment imposed upon the defendant as a result of the misconduct . . ." Defendants offered no evidence in this case that they had received "other punishment" as a result of proceedings similar to this case. This criterion was not relied upon by any of the parties and does not require the court to act with respect to it.

Appendix A

As stated by Justice Kennedy, concurring in *TXO Production Corp. v. Alliance Resources Corp.*, __ US __, 113 SCt 2711, 725 [sic] (1993), punitive damages must reflect "a rational concern for deterrence and retribution" rather than "bias, passion or prejudice by the jury." The punitive damages assessed against defendants in this case do reflect a rational concern for deterrence. There is nothing in this case that reflects bias, passion or prejudice by the jury toward the defendants. Rather, the jury engaged in a dispassionate effort (they deliberated for approximately 8 hours) to decide the issues in the case and to assess an amount of punitive damages that would get defendants' attention in a way that the FDA had been unable to achieve for years.

There is nothing presented by defendants that persuades me that they are entitled to a new trial or to a remittitur of the punitive damages assessed by the jury.

APPENDIX B — OR. REV. STAT. § 30.925 (1979)

ORS 30.925

Punitive damages. (1) In a product liability civil action, punitive damages shall not be recoverable unless it is proven by clear and convincing evidence that the party against whom punitive damages is [sic] sought has shown wanton disregard for the health, safety and welfare of others.

(2) During the course of trial, evidence of the defendant's ability to pay shall not be admitted unless and until the party entitled to recover establishes a prima facie right to recover under subsection (1) of this section.

(3) Punitive damages, if any, shall be determined and awarded based upon the following criteria:

(a) The likelihood at the time that serious harm would arise from the defendant's misconduct;

(b) The degree of the defendant's awareness of that likelihood;

(c) The profitability of the defendant's misconduct;

(d) The duration of the misconduct and any concealment of it;

(e) The attitude and conduct of the defendant upon discovery of the misconduct;

(f) The financial condition of the defendant; and

(g) The total deterrent effect of other punishment imposed upon the defendant as a result of the misconduct, including, but not limited to, punitive damage awards to

persons in situations similar to the claimant's and the severity of criminal penalties to which the defendant has been or may be subjected. [1979 c. 866 § 3]

[Note: Or. Rev. Stat. § 30.925 was amended in 1995, c.688 § 4. With that amendment, Or. Rev. Stat. § 30.925(3) became Or. Rev. Stat. § 30.925(2).]

APPENDIX C — OR. REV. STAT. § 18.537 (1995)

ORS 18.537

Standards for award of punitive damages; required review of award by court; additional reduction of award for remedial measures. (1) Punitive damages are not recoverable in a civil action unless it is proven by clear and convincing evidence that the party against whom punitive damages are sought has acted with malice or has shown a reckless and outrageous indifference to a highly unreasonable risk of harm and has acted with a conscious indifference to the health, safety and welfare of others.

(2) If an award of punitive damages is made by a jury, the court shall review the award to determine whether the award is within the range of damages that a rational juror would be entitled to award based on the record as a whole, viewing the statutory and common-law factors that allow an award of punitive damages for the specific type of claim at issue in the proceeding.

(3) In addition to any reduction that may be made under subsection (2) of this section, upon the motion of a defendant the court may reduce the amount of any judgment requiring the payment of punitive damages entered against the defendant if the defendant establishes that the defendant has taken remedial measures that are reasonable under the circumstances to prevent reoccurrence of the conduct that gave rise to the claim for punitive damages. In reducing awards of punitive damages under the provisions of this subsection, the court shall consider the amount of any previous judgment for punitive damages entered against the same defendant for the same conduct giving rise to a claim for punitive damages. [1995 c.688 §2]

APPENDIX D — TRIAL EX. 3, NOTICE OF ADVERSE FINDINGS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

JAN 27 1989

Robert P. Luciano
Chairman and Chief Executive Officer
Schering-Plough Corporation
1 Giralda Farms
Madison, NJ 07940

Notice of Adverse Findings

Dear Mr. Luciano:

Please refer to your current promotional campaign for THEO-DUR (theophylline anhydrous). We have conducted a review of this campaign after receiving an industry complaint. Although we informed your firm by letter dated February 26, 1987 of our objections to false and/or misleading claims of superiority for THEO-DUR relative to competing products, we find that your firm continues to employ claims we have previously described as false and/or misleading as well as new false and/or misleading claims.

These claims are being disseminated by a variety of promotional vehicles, including "Dear Doctor" letters, "Dear Pharmacist" letters, and brochures, as well as "presentations" sponsored by

your firm at local pharmacy association meetings. Promotional presentations in the form of press kits, media appearances, seminar presentations or publications sponsored solely by a firm are subject to Agency jurisdiction as labeling under Section 201(m) of the Federal Food, Drug and Cosmetic Act (the Act), or as advertisements under Section 502(n) of the Act.

Therefore, we have concluded that your firm has disseminated false and misleading labeling, which causes THEO-DUR to be misbranded under Sections 502(a) and 201(n) of the Act. Section 502(a) provides that "[a] drug . . . shall be deemed to be misbranded if its labeling is false or misleading in any particular." Section 201(n) provides that "If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material in the light of which representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual."

We have also concluded that your firm has disseminated advertisements which cause THEO-DUR to be misbranded under Section 502(n) of the Act due to the absence in such advertisements of a brief summary of side effects, contraindications, and effectiveness meeting the requirements of FDA regulations, 21 CFR 202.1(e).

Appendix D

Review of Promotional Claims

1. Your firm sponsored numerous promotional presentations for THEO-DUR by a California physician to various pharmacy associations. These presentations were attended by members of your sales force. The physician's comments contain numerous falsehoods, as well as a broad range of misrepresentations and innuendo regarding competing products, Agency approval under Section 505(j) of the Act, and the comparative safety and efficacy of "generic" vs. "pioneer" products. Among these statements are the following:

   a. In approving long-acting theophylline preparations as bioequivalent, FDA "requires only that the active ingredient be the same."

   b. Treatment failures have been documented that were directly attributable to substitution from THEO-DUR to other AB-rated theophylline products.

   Your firm is well aware of the false and misleading nature of such presentations, and we consider your firm's participation in dissemination of such comments to constitute a clear violation of the Act. Although the physician enjoys the right of free speech, your firm is prohibited by law from sponsoring promotional presentations that are false, misleading, or lacking in fair balance.

   In our February, 1987 letter to your firm, we requested that you stop your sales force's use of a video tape containing the same type of falsehoods, misrepresentations, and innuendo. As you know, we consider requests for immediate cessation of any promotional activity to be indicative of grave concerns on our part, and we are especially concerned by your firm's subsequent dissemination of similar claims by means of an "expert" in this manner.

Appendix D

The Agency has even greater concern when the person speaking at media appearances or seminars delivers a false and/or misleading message on an ongoing basis under the firm's continuing sponsorship, with the firm thereby being aware of the nature of the presentation. A press announcement or sponsorship of a media appearance, seminar, or sole-sponsored publication should not be viewed as an opportunity to engage in promotional activities that would be considered false or misleading under the Federal Food, Drug And Cosmetic Act if conducted by your sales force or other persons employed by your firm.

Your firm may sponsor educational activities that provide for mention of your products, involve discussions of extra-labeled uses, and present data favorable to your products relative to competing products. We have, in practice, not required dissemination of full prescribing information as part of this legitimate exchange of scientific information where the information is presented in a manner that is rigorously truthful, non-promotional, objective, and balanced. If a body of data includes significant evidence favoring competing products, a balanced and objective discussion of that data in an educational context will necessarily require discussion of those advantages of competing products as an integral component of a balanced presentation. This general standard applies to the overall presentation, including content and emphasis, as related both to your firm's products and competing products.

A firm's responsibility to assure fair balance in promotional activities is mandated by the Act and universally accepted. However, educational activities are routinely prepared and presented by medical and scientific experts functioning independently from the sponsoring firm; some may see this situation as precluding any effort

by the sponsoring firm to assure objectivity and balance. Firms do, however, prospectively ensure such objectivity and balance by providing for participation of experts known to be respected and objective, by providing for peer review of their findings where appropriate, and by informing the participants and any intermediaries of the firm's and the Agency's insistence upon objectivity and balance.

2. Your firm has disseminated the following promotional claim in recent "Dear Pharmacist" letters:

   "Of all sustained release oral theophyllines, only THEO-DUR (theophylline anhydrous) Sustained Action Tablets provides zero-order absorption."

   Agency experts rejected your firm's request to describe the product's absorption as "zero-order" in the product's labeling. We consider this claim false and/or misleading.

3. Your firm has recently initiated dissemination of promotional materials based upon a study conducted by Baker, et al which compared response in patients administered different controlled-release theophylline products. Your brochures and letters based upon this study prominently present a wide range of open-ended comparative claims to the effect that substitution from THEO-DUR to other controlled-release theophylline products has been shown to entail considerable hazard to patients.

   This study was limited to THEO-DUR and controlled-release theophylline products that are "B" rated in the Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book). "B" rated products are "drug products that FDA does not at this time consider to be therapeutically equivalent to other pharmaceutically equivalent products. . . ."

However, products are available that are "A" rated and considered therapeutically equivalent to THEO-DUR, and those products were not tested in this study. Therefore, your open-ended superiority claim that THEO-DUR is superior to these other "A" rated products is false and/or misleading under Section 201(n) of the Act.

We also consider the report of the Baker study to be seriously flawed, since it fails to recognize the availability of "A" rated products that can be substituted for THEO-DUR.

Conclusion

Your firm has employed falsehoods, misrepresentations, and innuendo, on a continuing basis and in the absence of any valid scientific data, in an effort to convince the medical and pharmaceutical communities that THEO-DUR is superior to all alternative controlled-release theophylline products. We have communicated such concerns in this regard to your firm previously. Therefore, we request that your firm do the following:

1. Immediately cease promotion of THEO-DUR as discussed above, and any and all other promotional activities by persons acting by or on behalf of your firm involving similar or otherwise false or misleading claims for THEO-DUR.

2. Immediately cease all distribution of the report of the study conducted by Baker, et al. Any promotional mention of that study should include a prominent statement (not a footnote) to the effect that "This study did not provide for administration of any of the available controlled-release theophylline products demonstrated to be therapeutically equivalent to THEO-DUR."

Appendix D

3. Provide a formal statement to FDA regarding the above actions.

Please respond within ten (10) working days of receipt of this letter with regard to steps taken as requested above. Depending upon your response, the Food and Drug Administration is prepared to initiate legal action to enforce the law which provides for, among other things, seizure of products found to be misbranded, injunctive relief to prevent future violations, and criminal prosecution.

Sincerely yours,

/s/
Kenneth R. Feather
Acting Director
Division of Drug Advertising
and Labeling
Office of Drug Standards

cc: Alexander R. Giaquinto, Ph.D.
Vice President, Regulatory Affairs
Schering-Plough Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033